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*EAR, NOSE and THROAT journal*

## Novafed® A

**Capsules** Each capsule contains pseudoephedrine hydrochloride 120 mg, chlorpheniramine maleate 8 mg

### Brief Prescribing Information

**CONTRAINDICATIONS:** Patients with severe hypertension, severe coronary artery disease, and in patients on MAO inhibitor therapy, narrow-angle glaucoma, urinary retention, peptic ulcer, during an asthmatic attack.

**Hypersensitivity:** Contraindicated in patients with hypersensitivity or idiosyncrasy to sympathomimetic amines or phenanthrene derivatives.

**Nursing Mothers:** Contraindicated because of the higher than usual risk for infants from sympathomimetic amines.

**WARNINGS:** Use judiciously and sparingly in patients with hypertension, diabetes mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy. May produce CNS stimulation and convulsions or cardiovascular collapse with accompanying hypotension.

Use with caution in patients with increased intraocular pressure, cardiovascular disease, hypertension or in patients with a history of bronchial asthma. Do not exceed recommended dose.

**Use in Elderly:** The elderly (60 years and older) are more likely to have adverse reactions to sympathomimetics. Overdosage in this age group may cause hallucinations, convulsions, CNS depression and death.

**PRECAUTIONS: General:** Should be used with caution in patients with diabetes, hypertension, cardiovascular disease and hyperreactivity to ephedrine. The antihistaminic may cause drowsiness and ambulatory patients who operate machinery or motor vehicles should be cautioned accordingly.

**Information for Patients:** Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery, and mental alertness in children.

**Drug Interactions:** MAO inhibitors and beta adrenergic blockers increase the effect of sympathomimetics. Sympathomimetics may reduce the antihypertensive effects of methyldopa, mecamylamine, reserpine and veratrum alkaloids. Concomitant use of antihistamines with alcohol, tricyclic antidepressants, barbiturates and other CNS depressants may have an additive effect.

**Pregnancy Category C:** Animal reproduction studies have not been conducted with NOVAFED A capsules. It is also not known whether NOVAFED A capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. NOVAFED A capsules may be given to a pregnant woman only if clearly needed.

**Nursing Mothers:** Pseudoephedrine is contraindicated in nursing mothers because of the higher than usual risk for infants from sympathomimetic amines.

**ADVERSE REACTIONS:** Hyperreactive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness, or nausea. Patients sensitive to antihistamines may experience mild sedation. Sympathomimetic drugs have been associated with certain untoward reactions including fear, anxiety, tenseness, restlessness, tremor, weakness, pallor, respiratory difficulty, dysuria, insomnia, hallucinations, convulsions, CNS depression, arrhythmias, and cardiovascular collapse with hypotension.

Possible side effects of antihistamines are drowsiness, restlessness, dizziness, weakness, dry mouth, anorexia, nausea, headache, nervousness, blurring of vision, heartburn, dysuria and very rarely dermatitis. Patient idiosyncrasy to adrenergic agents may be manifested by insomnia, dizziness, weakness, tremor or arrhythmias.

**OVERDOSAGE:** Acute overdosage with NOVAFED A capsules may produce clinical signs of CNS stimulation and variable cardiovascular effects. Pressor amines should be used with great caution in the presence of pseudoephedrine. Patients with signs of stimulation should be treated conservatively.

**DOSAGE AND ADMINISTRATION:** One capsule every 12 hours. Do not give to children under 12 years of age.

**CAUTION:** Federal law prohibits dispensing without prescription.

Product Information as of October, 1981

MERRELL DOW PHARMACEUTICALS INC.  
 Subsidiary of The Dow Chemical Company  
 Cincinnati, Ohio 45215, U.S.A.

**Merrell Dow**

3-1504 (3-0473) MNQ-341R



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